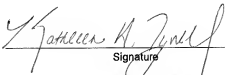


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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) KUZ-0021	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____	Application Number 10/517,468	Filed December 6, 2004	
	First Named Inventor Tatsuaki Suzuki		
	Art Unit 1615	Examiner Jeffrey T. Palenik	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. Registration number 38,350 <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____ <div style="text-align: right;"> _____ Signature Kathleen A. Tyrrell _____ Typed or printed name 856-810-1515 _____ Telephone number March 19, 2010 _____ Date</div>			
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			

<input checked="" type="checkbox"/> *Total of 1 forms are submitted.
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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REMARKS WITH PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 13, 5, 9, 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. (USP 6,139,866) and Tomaru et al. (USP 6,563,195). Claims 3, 4, 6-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. with respect to claim 13 as set forth above. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. and Tomaru et al. as set forth above with respect to claim 13 in combination with Nakahara et al. (JP 06-287134).

Appellant respectfully traverses these rejections.

Pending independent claim 13 recites a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer laminated thereon, wherein a side of said polyester-based film surface in contact with said drug-containing adhesive has a surface roughness (Ra) of from 0.05 to 0.8 μm thereby increasing anchoring between said polyester-based film and said drug anchoring adhesive layer without producing pinholes in said substrate. All other pending claims depend from claim 13.

Chono et al. has been acknowledged not to teach the instantly claimed PET film having a surface roughness ranging from 0.05 to 0.8 μm . See page 4 of Final Rejection mailed November 20, 2010. Dependent claims 3, 4, 6-9, 11 and 12 include this limitation. See MPEP 2143.03. Accordingly, further maintenance of the rejection of claims 3, 4, 6-9, 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. is improper as all claim limitations are not taught or suggested by Chono et al.

Also improper is the Examiner's reliance on Tomaru et al. simply for its teachings of the property that a film can be roughened to enhance its adherence.

MPEP 2141.03 is clear; a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Focus by the Examiner only upon the roughened film of Tomaru et al. and not its entire teachings is thus improper.

Further, Tomaru et al., when considered in its entirety, is nonanalogous art. MPEP 2141.01(a) states "to rely on a reference under 35 U.S.C. 103, it must be analogous prior art." The courts look to similarities and differences in structure and function of the inventions and similarities and differences in the problem to be solved to determine if the references are analogous. See, e.g., *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973); *Ex parte Bland*, 3 USPQ2d 1103 (Bd. Pat. App. & Inter. 1986); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *In re Mlot-Fijalkowski*, 676 F.2d 666, 213 USPQ 713 (CCPA 1982); *Stevenson v. International Trade Comm.*, 612 F.2d 546, 550, 204 USPQ 276, 280 (CCPA 1979); *In re Bigio*, 381 F.3d 1320, 1325-26, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004); *In Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985); *Ex parte Goodyear Tire & Rubber Co.*, 230 USPQ 357 (Bd. Pat. App. & Inter. 1985); *Medtronic, Inc. v. Cardiac Pacemakers*, 721 F.2d 1563, 220 USPQ 97 (Fed. Cir. 1983); and *Ex parte ROBERT C. DART, RYAN P. GINGRAS and TODD ATKINS Appeal 2007- 1325 Application 101065,722 Technology Center 3781*. In all of these cases the Courts compared similarity of the problem being solved by the claimed invention and the cited reference and/or structural similarities between the claimed invention and the cited reference to determine whether or not the cited reference was analogous as required by MPEP 2141.01(a).

Not only is the invention of Tomaru et al. (wafer support used for fixing a semiconductor wafer in a processing room of device production apparatus and method for producing and using such wafer support) classified differently in U.S. Class 257, subclass 620 as compared to the instant invention (patch formulations for drug delivery) in U.S. Class 424, subclass 443, but the structure, function, and problem being solved in the invention of Tomaru et al., are completely different.

The instant application states at page 6 that "the object of the invention is to solve the problems of the prior arts . . . to provide a patch which is free of any migration of drug into a substrate and shows favorable anchoring properties between the substrate and an adhesive layer, in which the drug containing adhesive layer is firmly adhered onto the substrate and which remains no adhesive residue when applied to the skin and then peeled off." Also at page 6 it is disclosed that "the inventors surprisingly found out that the anchoring properties between a substrate and an adhesive layer is improved by using a polyester-based film having the surface roughness of a specially fixed value" Favorable anchoring properties are described at page 2 of the instant application as "firm adhesion between the substrate and the adhesive and no adhesive residue when peeled off from the skin."

In contrast, Tomaru et al. states that their invention resolves the "problem that particles adhere to the front and/or rear surface of a [semiconductor] wafer in the production process" (col. 1, l. 19-24) by "providing a special dustproof covering film on the silicon rubber surface of a wafer support of the type which has the silicone rubber layer on a base made of ceramic and/or metal and peeling the dustproof covering film apart from the silicone rubber layer immediately before use" (col. 1, l. 61 - col. 2, l. 2).

The problem of preventing particles from adhering to a semiconductor wafer surface and the solution of a dustproof covering film which peels apart from the silicon rubber surface of a wafer support is in no way similar to the problem of improving anchoring properties of firm adhesion between a substrate and an adhesive layer of a transdermal drug delivery patch so that no adhesive residue remains when the patch is peeled off from the skin. In fact, the solution of Tomaru et al. of a dustcovering film which peels away from the device upon use is actually opposite to the problem solved in the instant invention of a patch with a substrate and drug-containing adhesive layer firmly adhered so that upon peeling of the patch from the skin, the drug-containing adhesive layer remains adhered to the substrate and not to the skin.

The structure and function of the invention of Tomaru et al. is also completely different. Tomaru et al. relates to a wafer support used for fixing a semiconductor wafer used in personal computers, game machines and cellular phones. At col. 1, l. 61-col. 2, l. 16, Tomaru et al. discloses the invention as dustproof covering film-attached wafer support comprising a base made of ceramic or metal, a silicone rubber layer substantially uniform in thickness and integrated with the base and a dustproof covering film, wherein the covering film is attached to the silicone rubber layer in a state that the covering film is capable of being peeled apart from the silicone rubber layer and the peel strength between the covering film and the silicone rubber layer is from 5 to 500 g/25 mm, measured by the peeling test according to JIS K 6854. In contrast, claim 13 is drawn to a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer laminated thereon, wherein a side of said polyester-based film surface in contact with said drug-containing adhesive has a surface roughness (Ra) of from

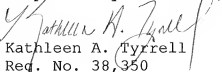
0.05 to 0.8 μm thereby increasing anchoring between said polyester-based film. The function of the patch is as a percutaneous absorption preparation to deliver a drug to a patient via adherence of the patch to the skin of the patient.

Since Tomaru et al. is classified differently and shares neither similarity of the problem being solved by the claimed invention nor structural or functional similarities, it is not analogous prior art and therefore it cannot be relied upon as a reference under 35 U.S.C. 103. MPEP 2141.01(a). The rejections under 35 U.S.C. 103(a) over the combined teachings of Chono et al. and Tomaru et al. and Chono et al., Tomaru et al. and Nakahara et al. (JP 06-287134), which also does not teach or suggest PET film having a surface roughness ranging from 0.05 to 0.8 μm , are therefore improper and must be withdrawn.

Appellant also demonstrates in the application at page 28 criticality of the narrower claimed range of surface roughness as compared to the broader range taught by Tomaru et al. in providing desired anchoring properties with no detachment of the polyester based film from the adhesive while producing no undesired pinholes. Neither of these are objectives of the nonanalogous reference of Tomaru et al. This demonstration clearly rebuts any prima facie case of obviousness over this reference when combined with Chono et al. and/or Nakahara et al.

Reconsideration and withdrawal of all rejections under 35 U.S.C. 103 is therefore respectfully requested.

Respectfully submitted,


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Date: March 19, 2010
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